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भारत सरकार

Financial Chronicle, Delhi
Saturday 1st March 2014, Page: 1
Width: 26.81 cms, Height: 30.44 cms, a3, Ref: pmin.2014-03-01.51.6

UNDER SCANNER

With their growing fame, Indian generic makers come under increased scrutiny by foreign regulators

- India is emerging as the second-largest supplier of drugs to the US with 40% market shore for generics
- In 2012, the country exported $4.2 billion worth of generic drungs to the United States
- Research data suggest that at least 5% of Indian medicines sold in India foil basic quality control tests

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Aditi Kare Panandikar, managing director at Indoco Remedies, said at a recent summit of pharma companies, "It is regular practice for the FDA to inspect facilities catering to its market. In case it raises some observations, both major and minor, it will issue a Form 483. While it is absolutely necessary for companies to maintain the quality standards, there is no reason for panic. Instead, the focus should be on doing the needful."

Indoco Remedies received a Form 483 for its Goa plant II (Sterile Ophthalmic Formulations) last year with certain "minor observations". The company says it has already responded to the FDA, which has since not reverted on the matter. More recently, however, the company posted on the Bombay Stock Exchange that it had received certificate of good manufacturing practice compliance for the same plant from the state institute for drug control (SUKL) of the Czech Republic.

Cipla's global head of quality Ranjana Pathak also stated recently, "Indian pharmaceutical companies are coming under the FDA ambit because they are not following all the rules specified in the guidelines. What is to be done is to simply follow the rules. If you make a mistake, it doesn't matter. Follow the rules which tell you how not commit those mistakes. Actually GMP makes for good business."

Besides Ranbaxy and Wockhardt, Bangalore-based Strides Arcolab also received an FDA warning for its injectible manufacturing arm Agila Specialties in 2013. In 2011, the Mexican unit of Dr Reddy's Laboratories received an import alert for violating manufacturing standards. However, the alert was withdrawn after the company initiated corrective measures.

In 2011, Aurobindo Pharmaceuticals received an import alert for violating manufacturing standards at two of its units. These were revoked in 2013 after the company took corrective steps. Earlier instances also show warning letters or observations were issued on manufacturing practices to Sun Pharmaceutical Industries, Cadila Pharmaceuticals, Lupin and Cipla.

Meanwhile, all these FDA actions have raised a counter-question as to whether Indian companies are being deliberately pulled up at the behest of global big pharma that has been losing market in their home countries? Both FDA and the Indian pharma industry reject that notion.

An official from Aurobindo Pharma, who did not wish to be named, said, "The rising diplomatic concerns are not referring to the compliance issues or inspections. What is important is to keep oneself aligned with this mindset and invest in the regulatory upkeep in line with expectations and to ensure that quality is not compromised. For Aurobindo, the focus has always been the advanced markets and we are committed to quality. A regulator has all the right to check even the slightest of deviation in standards. All our manufacturing sites cater to all the markets and are approved by global regulators. Sometimes it may happen that one particular site follows checks by the US FDA, but the UK MHRA may find a fault. It is based on several factors, sometimes as basic as what answers are given by the personnel located at the site."

After returning to the US from her recent nine-day India visit, FDA commissioner Margaret A Hamburg told the international media, "We are not (specifically) targeting Indian companies. We are undertaking our required regulatory activities. We inspect and take appropriate actions for companies within the US. If a company is manufacturing a product for sale in the US, it has to meet our regulatory standards and requirements and we inspect facilities in other countries as well. So, what is happening in India is consistent with what happens in the US and other parts of the world."

In an exclusive interview with *Financial Chronicle*, Hamburg said, "Many Indian firms understand good manufacturing practices and use them. The problems we have seen with companies are why we have chosen to make quality one of our highest priorities this year. Whether innovator or generic, companies must build their reputation by building quality so that patients and healthcare professionals have trust in their products. Quality is the basis of the public's confidence in pharmaceuticals and confidence in the high quality of products being produced at American facilities is what has helped make the US pharmaceutical industry the gold standard for the world." (Read full interview in this issue).

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Regulatory